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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,441	11/19/2003	J. Donald Hill	018880.0147	3943

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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11/30/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/715,441	Applicant(s) HILL ET AL.	
	Examiner Kathleen Sonnett	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-22, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-22 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 13-19 have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendment to claim 13. After further consideration, claims 20 and 35, which were previously indicated as being allowable, have been rejected as being anticipated by Berreklouw (WO 00/24339) and Berg et al. (US 6,074,416), respectively.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 18 and 19** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 recites the limitation "said first tissue clamp" in lines 2 and 3. Claim 19 recites the limitation "said second tissue clamp" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 13-21** are rejected under 35 U.S.C. 102(b) as being anticipated by Berreklouw (WO 00/24339). Berreklouw discloses a method of connecting two conduits comprising the

steps of positioning a first saddle of a first coupler having a first channel within a first conduit so that a portion of the first coupler is positioned on an inside wall of the first conduit and another portion of the first couple is positioned on an outside wall of the first conduit, positioning a second saddle of a second coupler having a second channel within a second conduit so that a portion of the second coupler is positioned on an inside wall of the second conduit, and another portion of the second coupler is positioned on an outside wall of the second conduit, clamping the first conduit to the first saddle of the first coupler, clamping the second conduit to the second saddle of the second coupler and connecting the first and second coupler (see fig. 16 which shows the claimed structure positioned within two conduits with the wall of each conduit clamped between two portions a coupler).

6. Regarding claims 14 and 15, the method includes making a first incision and positioning the first saddle within the first conduit (p. 20, ll. 25-27). Berreklouw only expressly discloses making one incision (although two holes are shown in fig. 16) but because claims 15 and 14 each depend from 13, the designation of which conduit, saddle, and coupler is "first" and which is "second" can be changed so that the incision is made in the first or the second conduit.

7. Regarding claims 16 and 17, the step of clamping the first conduit to the first saddle comprises the step of heating a first tissue clamp to a transition temperature such that the first tissue clamp secures the first conduit between the first tissue clamp and saddle (p. 10, line 24 – p. 11, line 4, and p. 21, ll. 25 - p. 22, ll. 4, which discloses that the flanges of the devices of Berreklouw may be shape memory such that, when heated, they change configuration, locking the device in place).

8. Regarding claims 18 and 19, Berreklouw discloses legs formed on the saddles that are bent outward (extended in an outward direction) so that the first and second conduits are secured between the first saddle and coupler and the second saddle and coupler, respectively.

9. Regarding claim 20, Berreklouw discloses a method of connecting two conduits comprising the steps of positioning a first saddle of a first coupler having a first channel within a first conduit, positioning a second saddle of a second coupler having a second channel within a second conduit, clamping the first conduit to the first saddle of the first coupler, clamping the second conduit to the second saddle of the second coupler, and connecting the first coupler and second coupler wherein the step of connecting the first and second coupler comprises the steps of positioning the first flange of the first coupler in alignment with a second flange of the second coupler and crimping a clamping ring (208) around the two flanges to secure the two couplers together (see p. 33, ll. 6-24).

10. Regarding claim 21, the step of positioning a first flange of the first coupler in alignment with the second flange of the second coupler comprises the step of engaging a first mating surface (206) of the first coupler and a second mating surface (207) of the second coupler.

11. **Claim 35** is rejected under 35 U.S.C. 102(b) as being anticipated by Berg et al. (US 6,074,416). Berg discloses a method for delivering a coupler into a blood vessel, the coupler comprising a saddle (40, 54), a channel (33, 30), wherein the channel comprises a first end connected to the saddle and a second end, a tissue clamp (44, 56) positioned around the channel and a flange (34 formed at opposite end; see fig. 2) formed adjacent the second end of the channel, the method comprising the steps of engaging the channel of the coupler, engaging the tissue clamp and bending the tissue clamp away from the saddle, making an incision (64) into the blood vessel, delivering the coupler into the blood vessel through the incision, securing the saddle to the blood vessel and releasing the tissue clamp so that the tissue clamp conforms to the saddle (see fig. 10a-10c).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berreklouw.

Berreklouw discloses the method substantially as stated above including the step of connecting the first and second coupler. Berreklouw fails to disclose connecting the first and second couplers before the steps of positioning the first and second saddle in the first and second conduit, respectively. However, Berreklouw does disclose that the two couplers could be made as an integral piece, which would result in the two couplers being connected before the first and second saddles are positioned within the first and second conduits. Furthermore, applicant has not disclosed any advantage gained, purpose served, or problem solved by joining the couplers together before the positioning step as opposed to joining the couplers after the positioning step. One skilled in the art would have expected either order of the steps to perform the function of joining two conduits together equally well. Therefore, it would have been prima facie obvious to modify Berreklouw to connect the first and second couplers before the steps of positioning the first and second saddles in the first and second conduits because such a modification would have been considered a mere design consideration that fails to patentably distinguish the claimed invention from the prior art of Berreklouw.

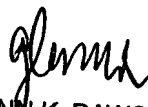
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 11/18/2007


GLENN K. DAWSON
PRIMARY EXAMINER